



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of New Animal Drug Applications; Nitarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of three new animal drug applications (NADAs) providing for the use of nitarsone in medicated feed for chickens and turkeys. This action is being taken at the sponsor's request because these products are no longer manufactured or marketed.

DATES: This rule is effective December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following NADAs that provide for the use of nitarsone in medicated feed for chickens and turkeys because the products are no longer manufactured or marketed:

| File No. | Product Name | 21 CFR Section |
|----------|---|----------------|
| 007-616 | HISTOSTAT 50 (nitarstone) Type A Medicated Article | 558.369 |
| 141-088 | HISTOSTAT 50 (nitarstone)/BMD (bacitracin methylene disalicylate) | 558.369 |
| 141-132 | HISTOSTAT 50/ALBAC (bacitracin zinc) | 558.369 |

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADAs 007-616, 141-088, and 141-132, and all supplements and amendments thereto, is withdrawn, effective December 31, 2015. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Parts 556

Animal drugs, Food.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.60 [Removed]

2. Remove § 556.60.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

§ 558.4 [Amended]

4. In § 558.4(d), in the "Category II" table, remove the entry for "Nitarstone".

§ 558.76 [Amended]

5. In § 558.76, remove and reserve paragraph (d)(3)(xiii).

§ 558.78 [Amended]

6. In § 558.78, remove and reserve paragraph (d)(3)(vii).

§ 558.369 [Removed]

7. Remove § 558.369.

Dated: December 11, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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